

## REMARKS

Applicant has carefully reviewed the Office Action mailed February 5, 2007 in which claims 1-38 are pending, claims 19-38 have been withdrawn from consideration and claims 1-18 have been rejected. Favorable consideration is respectfully requested.

### Claim Rejections under 35 U.S.C. § 102

Claims 1-4 and 7 were rejected under 35 U.S.C. § 102(e) as being anticipated by Deniega et al. (US 2004/0064129). Applicant respectfully traverses the rejection because Deniega et al. do not teach every element of the claimed invention.

The Deniega et al. patent pertains to a catheter designed to provide for a uniform distribution of fluid medication within an anatomical region. The embodiment of Figures 25-27 does this by providing a porous tubular section 280 which extends from a junction 278 distally from a non-porous tube 282 of the catheter. Paragraph 107. Deniega et al. teach that a distal end 285 of the non-porous tube 282 may be inserted into the lumen of porous tubular section 280 and that “preferably, a suitable type of medical adhesive is applied between the overlapping surfaces of the tube 282 and the tubular section 280, to hold the tubes 280, 282 together.” Paragraph 108.

The Examiner argues that “the adhesive layer is prepared and dried in an ambient environment and thus inherently has some void spaces and is capable of having distensible regions within the adhesive layer.” First, Deniega et al. do not teach that the adhesive layer is prepared and dried in an ambient environment. So far as Applicant can determine, Deniega et al. are silent as to the production environment. However, even if this were true, the results do not inherently follow. “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP

2112 citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). It is not necessarily the case in preparing and drying an adhesive layer in an ambient environment that voids are introduced into the adhesive. Indeed, in many manufacturing processes, one would expect the introduction of an inadvertent void to be relatively rare. Such a void might well reduce the strength of the bond or, where such a feature is desired, the transparency or other optical properties of the finished piece and thus be grounds for rejecting the piece in the inspection process. In Applicant's experience, which Applicant has no reason to think is uncommon, it is also quite easy to use an off-the-shelf adhesive to attached two components without introducing any voids into the adhesive. Deniega et al. thus do not teach "an aerated adhesive layer" as claimed in claim 1. For at least this reason, Applicant submits that claim 1 is allowable over Deniega et al. As claims 2-4 and 7 depend from claim 1 and contain additional elements, Applicant submits that these claims are in condition for allowance as well.

#### **Claim Rejections under 35 U.S.C. § 103**

Claims 5-6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Deniega et al. in view of Ferrara et al. (US 2001/0026666). Applicant respectfully traverses the rejection.

Claims 5-6 depend from claim 1, which claims "an aerated adhesive." As discussed above, Deniega et al. do not teach, expressly or inherently, an aerated adhesive. Ferrara et al. likewise fail to teach this element. The teaching of Ferrara et al. that the adhesive may be "an epoxy, a UV curable adhesive, or a cyanoacrylate adhesive" does not require that the adhesive be an aerated adhesive. Therefore, for at least the reason that neither Deniega et al. nor Ferrara et al. teach or suggest, singly or together, each and every element of the claimed invention, Applicant respectfully submits that claims 5-6 are in condition for allowance.

Claims 8 and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Deniega et al. in view of Ferrera et al. Applicant respectfully traverses this rejection. First, as discussed above, neither reference teaches an adhesive that is aerated or that has voids. Second and in part due to the fact that neither reference teaches an adhesive that is aerated or has voids, neither reference teaches that the percent volume of the voids or the effective density of the adhesive layer relative to the adhesive material is a result effective variable and thus a variable for which there is an optimum non-zero value. There is thus no teaching or suggestion of an aerated adhesive nor is there a suggestion or motivation to create an aerated adhesive found in the cited references. For at least these reasons, and the reason that these claims depend from claim 1 and contain additional elements, Applicant submits that these claims are in condition for allowance.

Claims 9-12 were rejected under 35 U.S.C § 103(a) as being unpatentable over Deniega et al. in view of Jauchen et al. (U.S. Patent No. 6,180,544). Applicant respectfully traverses the rejection.

As an initial matter, the Jauchen et al. reference is not a proper reference. To rely on a reference under 35 U.S.C. § 103, the reference must be analogous prior art. “To rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, be reasonably pertinent to the particular problem with which the inventor was concerned. MPEP 2141.01(a) citing *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). The field of Jauchen et al., self-stick plaster bandages and the like, is not in the field of the present application, catheters. Moreover, the Jauchen et al. reference cannot be said to be reasonably pertinent to the particular problem that the inventor of the present application is concerned with, namely bonding medical device components together

with an adhesive that resists stresses caused by adhesive curing. Applicant therefore respectfully submits that it is improper to rely on Jauchen et al. as a reference under 35 U.S.C. § 103.

Notwithstanding the impropriety of the rejection, the rejection of claims 9-12 over Deneiga et al. in view of Jauchen et al. nevertheless fails to establish a *prima facie* case of obviousness because there is no suggestion or motivation to modify the reference or combine reference teachings. The Examiner argues that it would have been obvious to use the adhesive of Jauchen et al. with the catheter of Deniega et al. because the adhesive allows for improved joining. However, nowhere in Deniega et al. is it suggested that an adhesive that improves joining would be desirable in the catheter of Deniega et al. Deniega et al. teach that their joining techniques are quite adequate and do not recognize the problem that the inventor of the present application recognizes of potential delamination of the adhesive joint. Correspondingly, there is no teaching that the adhesive of Jauchen et al., which improves the adhesion of a bandage to skin, would similarly improve joining between two components. Because the foamed adhesive of Jauchen et al. incorporates a substantial volume of air or other gasses in the form of voids or pockets, its strength per unit volume is necessarily lower than that of a non-foamed adhesive of the same material. The improved adhesion reported by Jauchen et al. therefore must come from an improved interface between the foamed adhesive and the skin. Foaming an adhesive produces an adhesive material with an irregular surface that is easily conformable, and one can infer that such a surface increases the surface area of adhesive that is actually sticking to the skin and that the improved adhesion reported comes from this increased area of adhesive that is in contact with the irregular surface of the skin. One also notes that the adhesive layer of the bandage, when it is stuck to the skin, is in a solid (and not a liquid) state. Thus one can see that the factors which make the foamed adhesive an improved adhesive for the purposes of Jauchen

et al. are inapplicable to the manufacture of catheters. In the manufacture of catheters, such as those of Deniega et al., the two components are fixed together with the adhesive in a liquid state and the adhesive is then cured with the components in place. There is thus no reason to suppose that a foamed adhesive would produce improved joining in the manufacture of a catheter. Applicant therefore respectfully submits that there is no motivation to combine the references and, consequently, that there is no *prima facie* case of obviousness. For at least this reason, Applicant respectfully submits that claims 9-12 are in condition for allowance.

Claims 14-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Deniega et al. Applicant respectfully traverses the rejection. No *prima facie* case of obviousness has been made because each and every claim element is not taught or suggested by the cited prior art, nor is there any suggestion or motivation to arrive at the claimed inventions from the prior art.

Claims 14-15 depend from claim 1, which recites “an aerated adhesive layer,” which, as described above with respect to the § 102 rejection of claim 1, is not disclosed by Deniega et al.

As to motivation, the Examiner argues that it would have been obvious to one of ordinary skill in the art to adjust the adhesive layer to desired thickness for optimal joining and reliability. However, “a particular parameter must be first recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” MPEP 2144.05 citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Applicant can find no indication in Deniega et al. that the gap between the two tubes is recognized as a result-effective variable; optimization of the gap therefore cannot be regarded as routine. To the contrary, Jauchen et al. teach that “preferably the tubular section 280 has an outer diameter of about 0.042 inches and has an inner diameter sized so that the distal end 285 of the tube 282 fits snugly

within the proximal end 287 of the lumen 281, as shown in Figure 26A.” Paragraph 110. In the other words, not only is the gap between these two tubes not a result-effective variable, it isn’t even a variable in the thinking of Jauchen et al. and it preferably doesn’t even exist.

Further, Applicant cannot see that the ranges claimed in claims 14-15 are optimal for the adhesives disclosed by Deniega et al. As Applicant discusses in paragraphs 3 and 4 of the specification, certain adhesives can exhibit shrinkage upon curing, which results in stresses building up in the adhesive layer. One solution (i.e., the prior art solution) to this is to limit the maximum thickness of the adhesive layer. Thus an optimal thickness for the adhesives in Deniega et al. would not be at least about .001 inch (as recited in claim 14) or in the range of about .002 inch to about .008 inch (as recited in claim 15), but as thin as practicable. This is consistent with the teaching of Jauchen et al. cited above that the one tube “fits snugly” within the other. For at least these reasons, Applicant submits that no *prima facie* case of obviousness has been made with respect to claims 14-15. For at least this reason and for the reason that these claims depend from claim 1, which Applicant submits is allowable, and contain additional elements, Applicant respectfully submits that these claims are in condition for allowance as well.

Claims 16-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Deniega et al. in view of Klima et al. (US 2001/0020161). Applicant respectfully traverses the rejection.

Claims 16-18 depend from claim 1 and contain additional elements. As discussed above, Deniega et al. do not disclose an aerated adhesive as recited in claim 1. Klima et al. do not remedy this deficiency. For at least these reasons, Applicant respectfully submits that these claims are in condition for allowance.

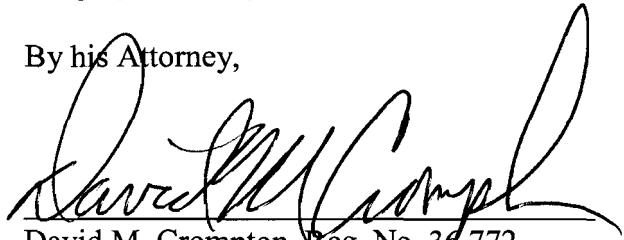
**Conclusion**

Examination of the above-identified claims is respectfully requested. If a phone conference is believed necessary to resolve any outstanding issues with respect to the above discussion, the Examiner is respectfully requested to contact the undersigned attorney.

Respectfully submitted,

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By his Attorney,



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